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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,839	02/21/2002	Yasufumi Kaneda	59150.8010	7050

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EXAMINER
CHEN, LIPING

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,839	KANEDA, YASUFUMI	
	Examiner	Art Unit	
	Liping Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 02/21/02 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the claims

A species election was made on 09/12/2002. Applicant's election without traverse of the species Paramyxoviridae, in Paper No. 7, is acknowledged. Claims 3, 25, 28, 32 and 35 are amended.

Claims 1-36 are pending and are examined only for Paramyxoviridae in this office action on the merits.

Priority

This is a 371 of PCT/JP01/00782 (02/02/2001).

Priority claimed to Foreign application JAPAN 2000-25596 filed 02/02/2000. However, there is no certified copy of the foreign priority document translation present. The examination is performed with priority to PCT international filing date (02/02/2001).

Objection

The disclosure is objected to because of the following informalities:

Fig. 7 is objected as there is no distinct band can be observed.

Fig. 13 is objected as there is no label for what the different bars stand for.

Fig. 14 is objected as it is unclear what bar-1 and bar-2 stand for.

Fig. 18 is objected as it is unclear what the different bars stand for.

The description of the drawings for Fig. 14 is objected to because it states "for squamous cell carcinomas (SAS) on the human tongue", which is read on *in vivo*. However, the description of Example 12 and 11 indicates it is an *in vitro* data.

p. 41, line 8-9, states "To a squamous cell carcinoma (SAS) on a human tongue, gene transfer was performed according to the method described in Example 11", which is read on *in vivo*. However, Example 11 is for *in vitro* gene transfer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-14 and 20-29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hoon et al. (U.S. Patent No. 6,472,375 B1, filing date of 08/31/1998 and issued 10/29/2002).

Claim 1 is directed to a gene transfer vector containing a virus envelope, claims 2-4 are further directed to the virus of claim 1 is derived from wild-type or

recombinant Paramyxoviridae such as HVJ; Claims 5-12 and 20-23 are directed to the gene transfer vector of claim 1; Claim 13 is directed to a pharmaceutical composition comprises a gene transfer vector containing a virus envelope, claims 24-26 are further directed to the virus of claim 13 is derived from wild-type or recombinant Paramyxoviridae such as HVJ; Claim 14 is directed to a kit comprises a gene transfer vector containing a virus envelope, claims 27-29 are further directed to the virus of claim 14 is derived from wild-type or recombinant Paramyxoviridae such as HVJ.

Hoon et al. ('375) teach a viral liposome vector comprising fused HVJ, which contains viral envelope, with nonviral reagents for delivery of nucleic acid encoding a tumor-associated antigen ('375, col. 3, line 5-9 and Fig. 1) into tumors or organs ('375, col. 5, line 66 to col. 6, line 2) such as mouse skeletal muscle ('375, col. 13, line 29) and mouse spleen ('375, col. 14, line 57), and a vaccine composition (it is a pharmaceutical composition or a kit) comprising the viral liposome vector for suppressing or attenuating tumor growth or treating cancer ('375, col. 2, line 65-67, and col. 3, line 20-22). Thus, Hoon et al. clearly anticipates the claimed invention.

Claims 5-10 and 20-23 are product-by-process claims. It is noted that product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Further, claims 11 and 12 are recite an intended use of the gene transfer vector of claim 1, and claims 14, 27-29 are recite an intended use of a kit comprising a gene transfer vector containing a virus envelope. It is noted that an intended use of a product is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02).

Claims 1-14, 18, 20-29 and 31-33 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Olson (U.S. Patent No. 6,372,957 B1, filing date of 11/10/1999 and issued 04/16/2002).

Claim 1 is directed to a gene transfer vector containing a virus envelope, claims 2-4 are further directed to the virus of claim 1 is derived from wild-type or recombinant Paramyxoviridae such as HVJ; Claims 5-12 and 20-23 are directed to the gene transfer vector of claim 1; Claim 13 is directed to a pharmaceutical composition comprises a gene transfer vector containing a virus envelope, claims 24-

26 are further directed to the virus of claim 13 is derived from wild-type or recombinant Paramyxoviridae such as HVJ; Claim 14 is directed to a kit comprises a gene transfer vector containing a virus envelope, claims 27-29 are further directed to the virus of claim 14 is derived from wild-type or recombinant Paramyxoviridae such as HVJ; Claim 18 is directed to a method for introducing a gene into isolated animal tissue comprising preparing a gene transfer vector containing a virus method of claim 18 where the virus is derived from wild-type or recombinant Paramyxoviridae such as HVJ.

Olson ('957) teaches liposome-mediated nucleic acid delivery and expression of foreign DNA *in vitro* ('957, col. 21, ling 42-43) and *ex vivo* ('957, col. 22, line 48) by preparing a vector of fusion of liposome with HVJ ('955, col. 21, line 51-55), which contains viral envelope (pertaining to instant claims 1-14 and 20-29). Olson further teach that *ex vivo* gene application refers to the isolation of cells from an animal, the delivery of a nucleic acid into the cells *in vitro*, this may involve the surgical removal of tissue/organs from an animal ('957, col. 22, line 48-53) (pertaining to instant claims 18 and 31-33). Thus, Olson clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19 and 34-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Hoon et al. (U.S. Patent No. 6,472,375 B1, filing date of 08/31/1998 and issued 10/29/2002) in view of Jessee (U.S. Patent No. 6,020,202, issued 02/01/2000) and further in view of Dubensky, Jr. et al. (U.S. Patent No. 6,451,592 B1, filing date of 10/06/1997 and issued 09/17/2002).

Claim 19 is directed to a method for introducing an exogenous gene into a suspended cell comprising mixing the suspended cell with a gene transfer vector containing a virus envelope in the presence of protamine sulfate, and centrifuging the mixture; claims 34-36 are further directed to the virus of claim 19 is derived from wild-type or recombinant Paramyxoviridae such as HVJ.

The teaching of Hoon et al. is discussed above. However, Hoon et al. dose not teach introducing an exogenous gene into a suspended cell in the presence of protamine sulfate.

Jessee ('202) teaches a method of tranfection of suspension cell lines ('202, col. 5, line 33-34) by contacting cells with a transfection composition containing a cationic lipid and active or inactive envelope virus or a viral component and a nucleic acid ('202, col. 5, line 20-25). Jessee cures the deficiency of Hoon et al. in that it teaches to use a composition containing viral envelope for transfection of

suspension cells. However, Jessee does not teach contacting transfection composition with suspension cell lines in the presence of protamine sulfate.

Dubensky, Jr. et al. ('592) teach to use infectious vector particles to transfect suspension culture of packaging cells ('592, col. 41, line 48-51), and that protamine sulfate can be used to enhance the activity of the reconstituted virus ('592, col. 44, line 51-55). Dubensky Jr. et al. Cures the deficiency of Jessee in that it teaches to use protamine sulfate for increasing reconstituted viral activity.

One of skill in the art of gene transfer would be motivated to combine the teachings of Hoon et al. with the teaching of Jessee and Dubensky, Jr. et al. because Jessee teaches to use vector containing viral envelope for suspension cell transfection, and Dubensky, Jr. et al. teach that protamine sulfate can enhance the activity of a reconstituted virus. Therefore, at the time the invention was made it would have been prima facie obvious to used the vector taught be Hoon et al. to transfect suspension cells as taught by Jessee in the presence of protamine sulfate as taught by Dubensky, Jr. et al since the vector taught by Hoon et al. contains reconstituted viral envelope. Although, none of Hoon et al. and Jessee and Dubensky et al. teach to centrifugation the mixture, it is a common step of after cell transfection. Therefore, the method for introducing an exogenous gene into a suspended cell of instant invention is rendered obvious in view of Hoon et al. ('375), Jessee ('202) and Dubensky, Jr. et al. ('592).

Claims 15-17 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jessee (U.S. Patent No. 6,020,202, issued 02/01/2000) in view of Fields et al. (Virology, Lipincott Williams & Wilkins, 1996, page 1178, right col. first full parag.) and Harmsen et al. (Eur J Biochem, 149:591-600, 1985).

Claim 15 is directed to a method for preparing a gene transfer vector comprising a virus envelope, wherein the method comprises mixing the virus with an exogenous gene and freezing and thawing the mixture two or more times; Claim 17 is directed to the method of claim 15 further comprising the step of inactivating the virus; Claim 16 is directed to a method for preparing a gene transfer vector comprising a virus envelope, wherein the method comprises mixing the virus with an exogenous gene in the presence of a detergent, claim 30 is directed to the method of claim 16 further comprising inactivating the virus.

Jessee ('202) teaches a method for transfecting eukaryotic cells using lipid, viruses, and nucleic acid of transfecting composition by mixing lipid aggregates complexed with nucleic acids with virus through freeze-thaw cycles to incorporate viral components into the lipid aggregate ('202, col. 4, line 19-29, and col. 5, line 40-56.). Jessee ('202) further teaches enveloped virus including Paramyxoviridae ('202, col. 3, line 39) can significantly enhace the efficiency of cationic lipid-mekiated tranfection of eukaryotic cells ('202, col. 3, line 60-63, and col. 4, line 33-47) and inactive virus can be prepared by application of freeze-thaw cycles ('202, col. 9, line 26-29). Fields et al. teach that the Paramyxoviridae contain a lipid bilayer envelope

that is derived from the plasma membrane of the host cell in which the virus is grown (Fields, page 1178, right col. first full parag. line 1-3). Further, Harmsen et al. teach reconstitution of Sendai virus (HVJ) using non-ionic detergents Triton X-100 and octylglucoside (Eur J Biochem, Abstract). Since Paramyxoviridae contain a lipid bilayer envelope (taught by Fields), the method taught by Jessee ('202) is mixing lipid bilayer, DNA and virus by freeze-thaw cycles, one of skill in the art of gene transfer would be motivated to combine the teachings of Jessee and Fields et al. to omit lipid used in the vector preparation by mixing envelope virus with exogenous nucleic acid directly and applying freeze-thaw cycles to incorporate the nucleic acid with virus lipid bilayer envelope and to inactivate the virus at the same step. Further, since non-ionic detergents Triton X-100 and octylglucoside has been used to reconstitution of Sendai virus (HVJ), one of skill in the art of gene transfer would be further motivated to combine the teaching of Harmsen et al. to mix detergent with envelope virus for transfer vector preparation. The level of skill in the art is very high, such that one of skill in the art would be able to combine the teaching of Jessee ('202) with Fields and Harmsen et al. with a reasonable expectation of success. Therefore, at the time the invention was made it would have been prima facie obvious to modify the teaching of Jessee ('202) by mixing envelope virus with exogenous nucleic acid by freeze-thaw cycles or in the presence of detergent for transfer vector preparation.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Pauline Farrier, Patent Analyst, at (703) 305-3550. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

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